K082654

TAB 5

510(K) SUMMARY

Date of Submission	10 September, 2008 NOV 25 2008
Official Contact / Address of Manufacturing facility	Andrew P. Zeltwanger Manager, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 Phone: 724-387-7442 Fax: 724-387-7490
Proprietary Name	Enteral Only Extension Sets
Common/Usual Name	Tubes, Gastrointestinal (and accessories)
Classification Reference	21 CFR 876.5980
Classification	Class II
Appropriate Classification Panel	Gastroenterology / Urology
Product Code	KNT
Predicate Devices	Vygon Nutrisafe® Extension Tube (K991918) Kangaroo Enteral Feeding Extension Set (K973409)

Intended Use/Indications for Use

The Enteral Only Extension Set is intended for use as an extension set for nasogastric/oralgastric or gastric tube enteral feeding tubes, incorporating safety connectors which eliminate the risk of accidental connection of an I.V. system to the enteral system, or the enteral system to an I.V. system..

Patient Population/Environment of Use

The Enteral Only Extension Set is a sterile disposable for single patient use only.

Substantial Equivalence

This traditional 510(k) submittal demonstrates that the Enteral Only Extension Set is substantially equivalent to the Vygon Nutrisafe® Extension Tube (K991918), and the Kangaroo Enteral Feeding Extension Set (K973409).

Design verification tests were performed on the Enteral Only Extension Set as a result of the risk analysis and the product requirements. All tests were verified to meet the required acceptance criteria. Respironics has determined that the differences between the Enteral Only Extension Set and the predicate enteral set have no impact on the safety and effectiveness of the Enteral Only Extension Set and that all hazards were successfully mitigated.

Device Description

Physical Description and Usage

The Enteral Only Extension Set consists of flexible PVC tubing designed to connect existing feeding tubes (nasogastric, gastric, etc.) to various delivery systems including pumps and syringes. The basic set consists of tubing with an enteral connector (catheter tip) and either a luer lock connector or an oral syringe connector. Other variations include the basic sets with the addition of a stop cock or Y site, to allow the clinician to attach other equipment. One configuration (Model 95017-D) utilizes luer lock connections on either end of the extension set, to allow for the connection to existing enteral feeding tubes with luer fittings. Note that in this configuration the extension set does not utilize an oral syringe connection, to minimize the possibility of oral feeding solutions to be delivered into an IV line.

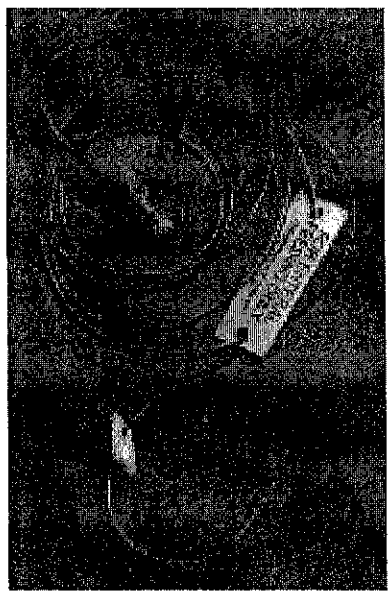
Descriptions of the different models are shown in Table 11-1. A photograph of a basic Enteral Only Extension Set is shown in Figure 11-1. Engineering drawings for all models are included at the end of Tab 11 – Device Description.

Table 11-1

Model	Description
95017-A	Extension Set w/Catheter Tip and Luer Lock Connector, 60"
95017-B	Extension Set w/Catheter Tip, Stop Cock and Luer Lock Connector, 60"
95017-C	Extension Set w/Catheter Tip, Y-site and Luer Lock Connector, 60"
95017-D	Extension Set w/Male and Female Luer Lock Connectors, 60"

95017-E	Extension Set w/Catheter Tip and Luer Lock Connector, 36"
1000364	Extension Set w/ Catheter Tip, Oral Syringe Y-Site, Luer Lock Connector, 60"
1017080	Extension Set w/ Oral Syringe Connector and Catheter Tip, 60"
1018514	Extension Set w/ Oral Syringe Connector and Catheter Tip, 36"
1018516	Extension Set w/ Stop Cock, Oral Syringe Connector and Catheter Tip, 60"
1018517	Extension Set w/ Y-Site, Oral Syringe Connector and Catheter Tip, 60"

Figure 11-1: Enteral Only Extension Set



Material Description

The Enteral Only Extension Sets are manufactured from polyvinyl chloride (PVC) tubing. The connectors and adaptors are manufactured of several plastics: PVC, acrylonitrile butadiene styrene (ABS), polyethylene (PE), polypropylene (PP), and polycarbonate (PC). All materials have been evaluated in accordance with ISO 10993-1 Biological Evaluation of Medical Devices -- Part 1: Evaluation and Testing. A biocompatibility assessment of the materials is included in Section 15 of this submittal.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 5 2008

Mr. Andrew P. Zeltwanger
Manager, Regulatory Affairs
Respironics, Inc.
Sleep and Home Respiratory Group
1740 Golden Mile Highway
MONROEVILLE PA 15146

Re: K082654
Trade/Device Name: Enteral Only Extension Set
Regulation Number: 21 CFR §876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: September 10, 2008
Received: September 12, 2008

Dear Mr. Zeltwanger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082654

Device Name: Enteral Only Extension Set

Intended Use/Indications for Use:

The Enteral Only Extension Set is intended for use as an extension set for nasogastric/oralgastric or gastric tube enteral feeding tubes, incorporating safety connectors which reduce the risk of accidental connection of an I.V. system to the enteral system, or the enteral system to an I.V. system.

Patient Population/Environment of Use:

The Enteral Only Extension Set is disposable and for single patient use only.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082654